REDACTED DOCUMENTS RELATED TO DOCKET 7341

7341 - Defendants' Motion and Memorandum in Support of Motion for Summary Judgment as to Plaintiff Carol Kruse's Claims - Filed Redacted

7344 - Defendants' Separate Statement of Facts in Support of Motion for Partial Summary Judgment as to Plaintiff Carol Kruse's Claims - Filed Redacted

Exhibit A - Filed Redacted

Exhibit C - Filed Redacted

Exhibit D - Filed Redacted

Exhibit E - Filed Redacted

Exhibit F - Filed Redacted

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00	13								
(404) 322-6000	14	IN THE UNITED STATES DISTRICT COURT							
(404)	15	FOR THE DISTRI	CT OF ARIZONA						
	16	IN RE: Bard IVC Filters Products Liability Litigation,	No. 2:15-MD-02641-DGC						
	17	Litigation,	DEFENDANTS' MOTION AND MEMORANDUM IN SUPPORT OF						
	18		MOTION FOR SUMMARY JUDGMENT AS TO PLAINTIFF						
	19		CAROL KRUSE'S CLAIMS						
	20		(A ' 1, 1 H 11 D '10						
	21	CAROL KRUSE, an individual,	(Assigned to the Honorable David G. Campbell)						
	22	Plaintiff,							
	23	v.	(Oral Argument Requested)						
	24	C. R. BARD, INC., a New Jersey							
	25	corporation and BARD PERIPHERAL VASCULAR, INC., an Arizona							
	26	corporation,							
	27	Defendants.							
	28								

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MOTION

Pursuant to Fed. R. Civ. P. 56, Local Rule 56.1, and Case Management Order No. 23 (Doc. 5770), Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard") respectfully move this Court for summary judgment as to Plaintiff Carol Kruse's product liability claims (Counts II, VI, VII, VIII, IX, XII, XIII, XIV¹) and her claim for punitive damages as alleged in the Master Complaint.² For the reasons stated below, Bard is entitled to judgment as a matter of law.

This motion is supported by Defendants' Memorandum of Points and Authorities and Separate Statement of Facts ("SSOF") which are filed herewith.

MEMORANDUM OF POINTS AND AUTHORITIES

I. Introduction.

Plaintiff Carol Kruse brings this product liability action for damages she claims to have suffered as a result of complications allegedly experienced related to a Bard G2® inferior vena cava ("IVC") filter, a prescription medical device that is designed to prevent potentially fatal pulmonary emboli. Before Ms. Kruse received her IVC filter,

Plaintiff claims that her Filter is defective because,

¹ The parties met and conferred regarding Plaintiff's claims. Plaintiff agreed she is not pursuing claims for manufacturing defect (Counts I, V), breach of express warranty (Count X), breach of implied warranty (Count XI), loss of consortium (Count XV), wrongful death (Count XVI), or survival (Count XVII). However, Plaintiff represented that she intends to pursue all of the claims addressed in this Motion.

² Plaintiff filed her original complaint on April 6, 2015, in the District Court for the District of Nebraska. Pursuant to Case Management Order No. 4, the Master Complaint is deemed pled in Plaintiff's case. (*See* Dkt. No. 363.)

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Notably, the potential for Ms.
Kruse's G2 Filter to migrate, perforate, tilt, fracture, and be unable to be retrieved are
risks that are well-known and accepted potential complications associated with all
retrievable IVC filters, and they are risks that Bard specifically warned about in the
Instructions for Use ("IFU") that accompanied Ms. Kruse's Filter. Moreover, Plaintiff's
implanting physician, Dr. Shanon Smith, testified that
he was aware of the potential complications associated with use of the device,
including the risks of tilt, migration, perforation, and fracture.

- Bard moves for summary judgment under Rule 56 on the following grounds:
- A. Plaintiff's claims are barred by Nebraska's 4-year statute of limitations.
- B. Plaintiff's claims are barred by the doctrine of judicial estoppel.
- C. Plaintiff's failure-to-warn claims (Counts II, VII) fail as a matter of law because Bard provided legally adequate warnings to a learned intermediary (Plaintiff's implanting physician), and any alleged failure to warn by Bard was not the proximate cause of Plaintiff's alleged injuries.
- D. Plaintiff's negligent post-sale duty to warn claim (Count VI) fails as a matter of law because Nebraska does not recognize a post-sale duty to warn.
- E. Plaintiff's negligence per se claim (Count IX) fails as a matter of law because such a claim cannot be based on alleged violations of a statute or regulation.
- F. Plaintiff's negligent and fraudulent misrepresentation/concealment claims (Counts VIII, XII, XIII) fail as a matter of law because there is no proof that Plaintiff or her implanting physician relied on an alleged misrepresentation or omission of material fact by Bard regarding the Filter.
- G. Plaintiff's consumer fraud claim (Count XIV) fails as a matter of law because the relevant statute awards injunctive relief, not money damages, and because the relevant statute applies only to claims based on alleged losses of business or

1	property, not personal injury claims.
2	H. Plaintiff's claim for punitive damage

H. Plaintiff's claim for punitive damages fails as a matter of law because Nebraska does not permit recovery of punitive damages in a civil case.

II. Statement of Undisputed Facts.

Plaintiff Carol Kruse

. (SSOF, ¶ 1.) The

Filter is a prescription medical device not available to the general public. (Id. at ¶ 2.) Ms.

Kruse

(Id. at ¶ 3.) According to Plaintiff's implanting physician,

Plaintiff has

(Id. at ¶ 4.)

Dr. Smith testified that before he placed the Filter, he had the IFU available to him to read. (*Id.* at ¶ 17.) The relevant IFU contains specific warnings regarding the risks of filter tilt, migration, fracture, perforation, and inability to retrieve, which are . (*Id.* at ¶¶ 18, 19.) Dr. Smith testified that he was independently aware of the risks of filter tilt, migration, perforation, and fracture, and that . (*Id.* at ¶ 20.) Notably, complications such as tilt, migration, perforation, fracture, and inability to retrieve are complications associated with all brands of retrievable IVC filters, not just Bard's IVC filters.

Ms. Kruse testified that,

27 (Id. at \P 6.) She also testified

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"personal property . . . of whatever kind." (Id. at ¶ 31.) Under No. 21 "Other contingent

³ Mr. Button is a former associate of Plaintiff's current lawyers.

and unliquidated claims of every nature," Ms. Kruse marked an "X" for "NONE." (Id. at ¶ 32.) Likewise, under No. 35 "Other personal property of any kind not already listed," Ms. Kruse marked an "X" for "NONE." (Id. at ¶ 33.) Ms. Kruse also filled out a Schedule in which she identified \$36,067.44 in creditor's unsecured, nonpriority claims. (Id. at ¶ 34.) Ms. Kruse signed the Petition, declaring under penalty of perjury that the information provided in the Petition is true and correct. (Id. at ¶ 35.)

On February 8, 2013, an Interim Trustee was appointed to Ms. Kruse's bankruptcy estate. (Id. at ¶ 36.) On April 1, 2013, after making a "diligent inquiry into the financial affairs" of Ms. Kruse, the trustee declared that he did not "receive[] any property" for the estate, and that "there is no property available for distribution," and he certified that Ms. Kruse's estate has been fully administered. (Id. at ¶ 37.) On June 3, 2013, Ms. Kruse obtained a bankruptcy discharge order. (Id. at ¶ 38.)

III. Summary Judgment Standard.

Summary judgment is appropriate when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "A moving party without the ultimate burden of persuasion at trial . . . has both the initial burden of production and the ultimate burden of persuasion on a motion for summary judgment." *Nissan Fire & Marine Ins. Co. v. Fritz Cos.*, 210 F.3d 1099, 1102 (9th Cir. 2000). "In order to carry its burden of production, the moving party must either produce evidence negating an essential element of the nonmoving party's claim or defense or show that the nonmoving party does not have enough evidence of an essential element to carry its ultimate burden of persuasion at trial." *Id.* "If . . . a moving party carries its burden of production, the nonmoving party must produce evidence to support its claim or defense." *Id.* at 1130-31 (internal citations omitted).

IV. Argument and Citation of Authority.

A. Plaintiff's Claims Are Barred by Nebraska's Statute of Limitations.

Plaintiff subjectively knew about her alleged Filter injury at least as early as March 14, 2011, which is the date

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(SSOF, ¶¶ 13, 14, 15.) Yet, Plaintiff waited more than 4-years until April 6, 2015, to file her Complaint. Plaintiff's claims are time-barred.

Nebraska has a 4-year statute of limitations for personal injury product liability actions. See Neb. Rev. Stat. § 25-224(1). The statute of limitations "begins to run on the date on which the party holding the cause of action discovers, or in the exercise of reasonable diligence should have discovered, the existence of the injury or damage." Thomas v. Countryside of Hastings, Inc., 524 N.W.2d 311, 313 (Neb. 1994) (internal quotation marks omitted). "Discovery refers to the fact that one knows of the existence of an injury or damage and not that one knows who or what may have caused that injury or damage." *Id.* Furthermore, a plaintiff "need not know the full extent of one's damages before the limitations period begins to run, as a statute of limitations can be triggered at some time before the full extent of damages is sustained." Gordon v. Connell, 545 N.W.2d 722, 726 (Neb. 1996); see also Reinke Mfg. Co. v. Hayes, 590 N.W.2d 380, 390 (Neb. 1999) ("A limitation period may begin to run even though the nature and extent of the damages are not known."). Moreover, the statute of limitations begins to run even if "the plaintiff may be ignorant of the existence of the cause of action." Cavanaugh v. City of Omaha, 580 N.W.2d 541, 544 (Neb. 1998).

Here, Plaintiff's claims against Bard accrued -- and the applicable statute of limitations began to run -- at the latest, on March 14, 2011. As of that date, Plaintiff subjectively knew that . Her actions up to and on that date undisputedly demonstrate Plaintiff's knowledge of her injury. Indeed, as of March 14, 2011, the following occurred:

- . (SSOF at \P 6);
- Plaintiff called an attorney about her potential IVC filter lawsuit after seeing a TV advertisement soliciting potential plaintiffs. (*Id.* at ¶ 10);
- Plaintiff called her daughter to discuss her Filter. (Id. at ¶ 12);
- Plaintiff discussed

Plaintiff may argue her claim did not accrue until April 7, 2011, when she had her . However, as noted above, Plaintiff did not need to know the full extent of her damages before her claim accrued. *See, e.g., Seagren v. Peterson*, 407 N.W.2d 790, 792 (Neb. 1987) ("[D]iscovery does not mean the final resolution of damages; it can be triggered at some time before the full extent of the damages is sustained."). Finally, Plaintiff may also argue that she did not know about alleged defects with her Filter, or that she had a cause of action against Bard, until sometime after March 14, 2011. But as noted above, Plaintiff did not need to know that she "has a legal right to seek redress" before her claim accrued. *See Gordon*, 545 N.W.2d at 726.

Because Plaintiff's claims against Bard accrued on or before March 14, 2011, and because Plaintiff waited until April 6, 2015, to file her lawsuit against Bard, Plaintiff's claims against Bard are time-barred by Nebraska's 4-year statute of limitations.

B. Plaintiff Should Be Judicially Estopped from Pursuing Her Claims.

Plaintiff petitioned for and received a full Chapter 7 Bankruptcy discharge in 2013, approximately two years after her claims against Bard accrued in 2011. (SSOF, ¶¶ 30, 37, 38.) Yet, when asked to identify under oath all of her property to the Bankruptcy Court, Plaintiff marked "NONE" for "contingent or unliquidated claims," and "NONE" for "other property." (*Id.* at ¶¶ 31, 32, 33, 35.) Plaintiff cannot reasonably dispute that she failed to identify in her Bankruptcy Petition her claims against Bard. Accordingly, her claims should be barred by the doctrine of judicial estoppel.

"Judicial estoppel is an equitable doctrine that 'prevents a party from asserting a claim in a legal proceeding that is inconsistent with a claim taken by that party in a previous proceeding." *Jones v. Bob Evans Farms, Inc.*, 811 F.3d 1030, 1032 (8th Cir. 2016) (quoting *New Hampshire v. Maine*, 532 U.S. 742, 749 (2001)). The Eighth Circuit

considers three factors when deciding whether to apply judicial estoppel to a party: (1) the party's later position must be "clearly inconsistent" with its prior position; (2) the party's position must have been accepted or adopted by a prior court; and (3) the party asserting inconsistent positions would derive some "unfair advantage" if not judicially stopped. *See Jones*, 811 F.3d at 1033. "A party who has filed for bankruptcy may be judicially estopped from pursuing a claim not disclosed in his or her bankruptcy filings." *Id.* Here, all three factors support application of judicial estoppel to bar Plaintiff's claims.

First, Plaintiff has taken inconsistent positions between her bankruptcy case and this case. She knew she had a "contingent" or "unliquidated" claim against Bard, yet she did not disclose it in her Petition. (SSOF, ¶¶ 31, 32, 33.) Even if this Court rejects Bard's statute of limitations argument and believes Plaintiff's claims against Bard accrued after March 14, 2011, at the very latest, her claims accrued on April 7, 2011,

(*Id.* at ¶¶ 16, 27.) Indeed, Plaintiff admits

(*Id.* at ¶ 16.) And Plaintiff's decision to file her lawsuit against Bard on April 6, 2015, one day shy of the 4-year anniversary of the removal procedure strongly suggests Plaintiff's and her counsel's subjective belief that her claim accrued at least by April 7, 2011. Plaintiff's failure to disclose her claims against Bard in her Petition is tantamount to "represent[ing] to the bankruptcy court that no such claims existed." *Jones*, 811 F.3d at 1033. Of course, here, she has taken the opposite position and asserted a claim against Bard. *See id.* (asserting claims that were earlier represented as not existing "is inconsistent" with the party's prior position).

Second, the Bankruptcy Court adopted Plaintiff's position when it discharged Plaintiff's debts. See id. (holding that a bankruptcy court adopted the debtor's position of the lack of a claim when the court discharged the debtor's debts); see also Van Horn v. Martin, 812 F.3d 1180, 1183 (8th Cir. 2016) ("[T]he bankruptcy court adopted [the plaintiff/debtor's] representation that no claims existed when it discharged \$18,391.49 of her unsecured debt."); (SSOF, ¶ 38). Thus, the second judicial estoppel factor is met here.

Third, Plaintiff clearly derived an unfair advantage in her bankruptcy proceeding

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by concealing her claims. Like the Eighth Circuit stated, "[i]f [Plaintiff] had disclosed [her] claims, for example, the trustee could have moved the bankruptcy court to order [her] to make the proceeds from any potential settlement available to [her] unsecured creditors." Jones, 811 F.3d at 1034; see also Cover v. J.C. Penney Corp., 187 F. Supp. 3d 1079, 1089 (D. Minn. 2016) (holding that the third factor was met where, by failing to disclose her claims in a bankruptcy proceeding, the plaintiff/debtor's "potential damages" arising from this lawsuit would go directly to her and not to her creditors").

Plaintiff may argue that her failure to disclose her claims against Bard in her Bankruptcy Petition was inadvertent and not intended to mislead the court. But the Eighth Circuit has already rejected this same argument, holding that "[a] debtor's failure to satisfy its statutory disclosure duty is 'inadvertent' only when, in general, the debtor either lacks knowledge of the undisclosed claims or has no motive for their concealment." *Jones*, 811 F.3d at 1034 (internal citations omitted).

Finally, Plaintiff may recognize that she is judicially estopped from asserting her claims, and she may ask this Court to allow the bankruptcy trustee to be substituted in as the real party in interest. However, even if she does make such a request, this Court is not obligated to allow a substitution. Where, as here, a plaintiff merely engages in "last minute candor" by seeking to reopen a bankruptcy estate and having a trustee pursue her claims, a trial court does not abuse its discretion in applying judicial estoppel to bar the claims. See Jones, 811 F.3d at 1032 & 1034 (holding that the trial court did not abuse its discretion in dismissing the plaintiff's claims pursuant to the judicial estoppel doctrine, where trial court concluded that the plaintiff's "last minute candor" was not enough to prevent application of the doctrine). In any event, as of the filing of this Motion, Plaintiff has not sought to reopen her bankruptcy estate, (see SSOF, ¶ 39), and the trustee has not sought to intervene in this matter. The issue of trustee intervention is not ripe at this moment. However, Bard notes that if the bankruptcy trustee were to seek to pursue Plaintiff's claims on behalf of her estate, any damages that could be recovered should be capped at an amount sufficient to satisfy Plaintiff's creditors and the costs and fees

incurred by the trustee. *See, e.g., Parker v. Wendy's Int'l, Inc.*, 365 F.3d 1268, 1273 n.4 (11th Cir. 2004); *Wiggins v. Citizens Gas & Coke Util.*, No. 1:03-CV-1882-SEB-JMS, 2008 WL 4530679, at *4 (S.D. Ind. Oct. 7, 2008); *Martin v. U.S. Bank*, No. 4:04CV01527AGF, 2005 WL 3107722, at *6 (E.D. Mo. Nov. 18, 2005).

C. The Learned Intermediary Doctrine Forecloses Plaintiff's Failure-to-Warn Claims (Counts II, VII) as a Matter of Law.

Plaintiff's failure-to-warn claims fail because Bard provided legally adequate warnings of the complications allegedly experienced by Plaintiff to a learned intermediary, Plaintiff's implanting physician, Dr. Smith. Moreover, Dr. Smith was independently aware of the

Finally, any alleged failure to warn by Bard was not the proximate cause of Plaintiff's alleged injuries

In Nebraska, "'[a] manufacturer or other seller is subject to liability for failing either to warn or adequately to warn about a risk or hazard inherent in the way a product is designed that is related to the intended uses as well as the reasonably foreseeable uses that may be made of the products it sells." *Rahmig v. Mosley Mach. Co.*, 412 N.W.2d 56, 72 (Neb. 1987) (quoting *Prosser and Keeton on the Law of Torts, Prods. Liab.*, § 96 at 685 (5th ed. 1984)). Furthermore, Nebraska has explicitly adopted the learned intermediary doctrine as stated in the *Restatement (Third) of Torts: Products Liability* § 6(d) (1997), which applies the doctrine to "[a] prescription drug or medical device." *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 842 (Neb. 2000) (quoting *Restatement (Third)* § 6(d)). Thus, a medical device manufacturer's "duty to warn extends only to members of the medical profession and not to the consumer." *Freeman*, 618 N.W.2d at 841.

As with other claims, to succeed on a failure-to-warn claim, a plaintiff has the burden of establishing causation. *See generally Stahlecker v. Ford Motor Co.*, 667 N.W.2d 244, 253 (Neb. 2003) (discussing causation requirement in product liability cases). "[I]f a user actually knows of the danger, a failure to warn cannot be a proximate cause of the injury. " *Crook v. Farmland Indus., Inc.*, 54 F. Supp. 2d 947, 958 (D. Neb. 1999); *see also Strong v. E. I. DuPont de Nemours Co.*, 667 F.2d 682, 688 (8th Cir. 1981)

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("If, despite deficient warnings by the manufacturer, a user is fully aware of the danger which a warning would alert him or her of, then the lack of warning is not the proximate cause of the injury." (applying Nebraska law)). This same rule applies in pharmaceutical drug and medical devices cases involving a learned intermediary. As the Eighth Circuit Court of Appeals has recognized, "[t]he learned intermediary doctrine provides that the failure of a drug manufacturer to provide the physician with an adequate warning of the risks associated with a prescription product is not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warnings should have communicated." Brinkley v. Pfizer, Inc., 772 F.3d 1133, 1137 (8th Cir. 2014)⁴ (internal quotation marks omitted). Similarly, to prove proximate causation, Plaintiff has the burden to prove that "a proper warning would have changed the decision of the treating physician, i.e. that but for the inadequate warning, the treating physician would not have used or prescribed the product." Ackermann v. Wyeth Pharm., 526 F.3d 203, 208 (5th Cir. 2008); see also Ingram v. Novartis Pharm. Corp., 888 F. Supp. 2d 1241, 1246–47 (W.D. Okla. 2012) (granting summary judgment to defendant in prescription drug case, where plaintiff failed to produce evidence that treating physician would have changed treatment decision had a proper warning been given); *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 995 (C.D. Cal. 2001) ("Pfizer may prevail in its motion for summary judgment if Ms. Motus has failed to adduce evidence that Dr. Trostler would have acted differently had Pfizer provided an adequate warning.").

Here, the Filter is a prescription medical device not available to the general public. (SSOF, ¶ 2.) Accordingly, the learned intermediary doctrine applies, and Bard only had a duty to warn Dr. Smith, of the risks of the Filter's use. Dr. Smith's testimony establishes that the warnings accompanying the Filter were

⁴ Although the court in *Brinkley* was applying Missouri law, the basic principle that a prescribing physician who has independent knowledge of the risks involved with the product breaks the chain of proximate causation applies as a general proposition of law. Indeed, the *Brinkley* court looked to and cited Arkansas and Florida law when discussing this general rule. See Brinkley, 772 F.3d at 1137.

adequate to warn him of Dr. Smith
testified that before he placed the Filter, he had the IFU that accompanied the Filter
available to him to read. (Id. at \P 17.) The relevant IFU contains specific warnings
regarding the risks of filter tilt, migration, fracture, perforation, and inability to retrieve,
which are (Id. at ¶ 18.) Under the
bolded heading "Potential Complications," the IFU reads as follows:

- Movement or migration of the filter is a known complication of vena cava filters.
- Filter fracture is a known complication of vena cava filters.
- Perforation or other acute or chronic damage of the IVC wall.

* * *

All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients.

(*Id.* at ¶ 19.a) (emphasis in original). Additionally, in the bolded "Clinical Experience" section, the IFU notes that in the clinical trial regarding the G2 Filter, "filter tilt" was observed 15 times, and that there were "3 technical failures for retrieval resulted from inability to engage the filter apex with the Recovery Cone® Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall." (*Id.* at ¶ 19.b) (emphasis in original). Finally, under the bolded "G2® Filter Removal" heading, the IFU states in bolded language as follows:

It is possible that complications such as those described in the "Warnings", "Precautions," and "Potential Complications" sections of this Instructions for Use may affect the recoverability of the device and result in the clinician's decision to have the device remain permanently implanted.

(*Id.* at ¶ 19.c) (emphasis in original). Because the IFU warned Dr. Smith regarding the relevant risks of using the Filter, Bard's warnings were legally adequate.⁵

⁵ Plaintiff may argue that Bard failed to warn Dr. Smith of the relative complication rates

In addition, Plaintiff has not established that any failure to warn by Bard was the proximate cause of her injuries. Dr. Smith testified he was independently aware of the risks of IVC filter tilt, migration, perforation, and fracture before he decided to use the Filter. (*Id.* at ¶ 20.) Additionally, although Dr. Smith testified on occasion that he may have wanted to know certain alleged factual information presented by Plaintiff's counsel, and that more information is helpful, (*see id.* at ¶ 21), he never testified that had he received some additional information from Bard, he would have used a different device with Plaintiff. (*Id.* at ¶ 22.) At most, he testified "it's possible" he would have changed his treatment of Plaintiff. (*Id.* at ¶ 23.) Finally, when asked whether the alleged facts and documents shown to Dr. Smith by Plaintiff's counsel would have changed his decision to Dr. Smith admitted that he "wouldn't want to say how they would influence me without knowing what they say in detail." (*Id.* at ¶ 24.)

In the absence of evidence establishing that a failure to warn was the proximate cause of Plaintiff's injury -- that is, that a different warning would have caused Dr. Smith to choose a different product -- Plaintiff's failure-to-warn claims fail as a matter of law.

D. Plaintiff's Negligent Post-Sale Duty to Warn Claim (Count VI) Fails as a Matter of Law Because Nebraska Does Not Recognize Such a Claim.

No court applying Nebraska law has recognized a post-sale duty to warn or retrofit. Instead, the Eighth Circuit has stated that "Nebraska would not impose either a post-sale duty to warn or a duty to retrofit." *Anderson v. Nissan Motor Co.*, 139 F.3d 599, 602 (8th Cir. 1998). The *Anderson* court based its opinion on the Nebraska Supreme Court decision in *Rahmig v. Mosley Mach. Co.*, 412 N.W.2d 56 (Neb. 1987). *See Anderson*, 139 F.3d at 602. In *Rahmig*, the Nebraska Supreme Court held that a plaintiff is not required to prove

of Bard's IVC filters compared to competitor devices. Such an argument would be misplaced. Under Nebraska law, a manufacturer has a duty to warn of "risk or hazard inherent in the way *a product* is designed," not to provide a warning regarding some other product. *See Freeman*, 618 N.W.2d at 841 (emphasis added) (internal quotation marks omitted). For the reasons and arguments stated at footnote 3, page 9 of Bard's Motion for Summary Judgment filed in *Jones v. C. R. Bard, Inc., et al.*, which are incorporated herein by reference, Bard had no legal duty to provide warnings to Dr. Smith regarding the rates of complications with the G2 Filter in comparison to any other product.

a feasible alternative safer design in a negligent design case, reasoning that to hold otherwise "unnecessarily invites perilous and unfairly prejudicial evidence of postaccident matters excludable under Neb. Evid. R. 407." *Rahmig*, 412 N.W.2d at 82. In dicta, the court also stated that "[i]n a products liability action, the plaintiff has the burden to prove that the alleged defect *existed when the product left the manufacturer*." *Id.* at 69 (as quoted in *Anderson*, 139 F.3d at 602 (emphasis added by *Anderson* court)). The *Anderson* court reasoned that "[t]he Nebraska Supreme Court's statements in *Rahmig* lead us to conclude that Nebraska favors limiting the state's products liability law to actions or omissions which occur at the time of manufacture or sale." *Anderson*, 139 F.3d at 602. Accordingly, the *Anderson* court affirmed the district court's decision to dismiss the plaintiff's post-sale duty to warn and retrofit claims pursuant to Rule 12(b)(6).

Because no Nebraska court has ever recognized a post-sale duty to warn or retrofit -- and because such a claim runs contrary to Nebraska Supreme Court's statements and reasoning in *Rahmig* -- this Court should decline to recognize such a claim here.

E. Plaintiff's Negligence Per Se Claim (Count IX) Cannot Be Based on Alleged Violations of a Statute or Regulation.

Plaintiff's negligence per se claim fails as a matter of clear Nebraska law. The Nebraska Supreme Court recently stated "that the violation of a regulation or statute is not negligence per se, but may be evidence of negligence to be considered with all the other evidence in the case." *Scheele v. Rains*, 874 N.W.2d 867, 872 (Neb. 2016); *see also In re Derailment Cases*, 416 F.3d 787, 795 (8th Cir. 2005) (affirming dismissal of negligence per se claims because "violation of a regulation or statute is generally not recognized as negligence per se under Nebraska law").

Here, Plaintiff's negligence per se claim (Count IX) is based exclusively on alleged violations of federal statutes and federal regulations. (*See* Master Complaint for Damages for Individual Claims [Dkt. No. 364] at ¶¶ 229-234.) Under clear Nebraska law, such alleged violations cannot form the basis of a negligence per se claim. Accordingly, Plaintiff's negligence per se claim fails as a matter of law.

F. Plaintiff's Negligent and Fraudulent Misrepresentation/Concealment Claims (Counts VIII, XII, XIII) Fail as a Matter of Law Because Plaintiff Cannot Prove the Essential Element of Reliance.

Reliance is an essential element of any negligent or fraudulent misrepresentation or concealment claim. *See Knights of Columbus Council 3152 v. KFS BD, Inc.*, 791 N.W.2d 317, 330-31 (Neb. 2010). Before a plaintiff can prove reliance, he or she "must have received the information" that allegedly was misrepresented by the defendant. *Id.* at 328. Accordingly, "plaintiffs cannot show reliance on a misrepresentation that never reached them and of which they had no knowledge." *Id.* Likewise, for a plaintiff to succeed on a concealment claim, the plaintiff must have first received some representation. *Id.* ("[A] plaintiff must have received the representation before the plaintiff can show that a defendant had a duty to disclose additional facts [to support a concealment claim].").

Here, Plaintiff's misrepresentation and concealment claims fail because she cannot prove the essential element of reliance. Ms. Kruse testified that she never spoke to anyone at Bard. (SSOF, \P 40.) She never received any written or verbal information about her filter before she received it. (*Id.* at \P 41.) She testified that she never researched IVC filters. (*Id.* at \P 42.) Finally, she testified that she did not even know that Bard was the manufacturer of her filter until

(*Id.* at ¶ 43.) Accordingly, the undisputed evidence demonstrates that Ms. Kruse did not receive any representation from Bard, and, thus, could not, as a matter of law, have relied on any alleged misrepresentation.

Additionally, Bard submits that whether Plaintiff's implanting physician relied on an alleged misrepresentation or omission should be irrelevant for purposes of Plaintiff's misrepresentation and concealment claims. However, even if his actions were relevant, Dr. Smith testified he relies on his training, experience, the experience of his colleagues, and the applicable medical literature when he makes treatment decisions regarding his patients, including Ms. Kruse. (Id. at ¶ 25.) He *did not* testify he relied on any statement by Bard -- or any omission of material fact -- in deciding to use the Filter. (Id. at ¶ 26.)

Neither Plaintiff nor her implanting physician testified that they relied on a material

misrepresentation -- or omission of material fact -- when deciding to use a Bard G2 Filter. Because Plaintiff cannot prove the essential element of reliance, her misrepresentation and concealment claims fail as a matter of law.

G. Plaintiff's Consumer Fraud Claim (Count XIV) Fails Because the Relevant Statute Awards Only Injunctive Relief, and Because the Statute Applies Only to Claims Based on Alleged Losses of Business or Property.

Nebraska has adopted the Uniform Deceptive Trade Practices Act ("UDTPA"), under Neb. Rev. Stat. § 87-301, *et seq.*, and the Consumer Protection Act ("CPA"), under Neb. Rev. Stat. § 59-1601, *et seq.* As a matter of law, Plaintiff cannot sustain her personal injury action against Bard based on alleged violations of those Acts.

Regarding the UDTPA, although it allows for private causes of action, the Act is explicitly limited to actions for injunctive relief. *See* Neb. Rev. Stat. § 87-303(a) ("A person likely to be damaged by a deceptive trade practice of another may bring an action for, and the court may grant, *an injunction* under the principles of equity against the person committing the deceptive trade practice." (emphasis added)). As the Nebraska Supreme Court has stated, "by its own terms, § 87–303(a) only provides for equitable relief consistent with general principles of equity." *Sid Dillon Chevrolet-Oldsmobile-Pontiac, Inc. v. Sullivan*, 559 N.W.2d 740, 746 (Neb. 1997). The Nebraska UDTPA "does not provide a private right of action for damages." *Vallejo v. Amgen, Inc.*, No. 8:14CV50, 2014 WL 4922901, at *5 (D. Neb. Sept. 29, 2014). Here, Plaintiff seeks monetary damages, not injunctive relief. (*See* Master Complaint [Dkt. No. 364] at "Prayer for Relief.") Accordingly, Plaintiff's UDTPA claim fails.⁶

With respect to the CPA, although the Act allows for private causes of action, the Act is explicitly limited to instances where a person "is injured in his or her business or property." Neb. Rev. Stat. § 59-1609. By its express terms, the CPA does not create a cause of action for personal injury claims. Here, Plaintiff's claim is for personal injury, not injury to her "business or property." Therefore, Plaintiff's personal injury product

⁶ Plaintiff also failed to comply with the notice requirements under § 87-303.12.

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monopolies, conspiracies in restraint of trade -- Plaintiff has never identified an alleged violation by Bard of one of the prohibited practices under the Act. Accordingly, Plaintiff's CPA claim fails as a matter of law.

liability claim cannot be based on alleged violations of the CPA. Finally, while the CPA

bars various forms of trade or business practices -- such as unfair competition,

H. Plaintiff's Claim for Punitive Damages Fails as a Matter of Law Because Nebraska Does Not Permit Recovery of Punitive Damages in a Civil Case.

"It is a fundamental rule of law in [Nebraska] that punitive, vindictive, or exemplary damages are not allowed. The measure of recovery in all civil cases is compensation for the injury sustained." Miller v. Kingsley, 230 N.W.2d 472, 474 (Neb. 1975); see Distinctive Printing & Pkg. Co. v. Cox, 443 N.W.2d 566, 574 (Neb. 1989) ("[P]unitive, vindictive, or exemplary damages contravene Neb. Const. art. VII, § 5, and thus are not allowed in this jurisdiction."). In light of Nebraska's "[c]lear constitutional prohibition" against punitive damages, Enron Corp., 940 F.2d at 313, the Court should grant summary judgment on Plaintiff's punitive damages claim. See Sanford v. Ektelon/Prince Sports Grp., Inc., No. 8:97CV368, 1999 WL 33537914, at *5 (D. Neb. Nov. 5, 1999) (granting summary judgment in light of Nebraska's "clear mandate" against punitive damages).

V. Conclusion.

For these reasons, Bard respectfully requests that this Court grant Bard's Motion for Summary Judgment.

⁷ Because the parties agree that Nebraska substantive law applies, the Court need not engage in a conflict-of-law analysis here. Nonetheless, even when faced with conflict-oflaw issues, courts overwhelmingly defer to Nebraska's "strong public policy interest in prohibiting punitive damages." Kammerer v. Wyeth, No. 8:04CV196, 2011 WL 5237754, at *5 (D. Neb. Nov. 1, 2011); see also Enron Corp. v. Lawyers Title Ins. Corp., 940 F.2d 307, 313 (8th Cir. 1991) ("[B]alancing Nebraska's clear constitutional prohibition against the Virgin Islands' adoption of the Restatement's position, we conclude that Nebraska has the most significant relationship to this case with respect to the issue of punitive damages."); *Bamford, Inc. v. Regent Ins. Co.*, No. 8:13CV200, 2014 WL 12539650, at *3 (D. Neb. June 12, 2014) ("Wisconsin's interest to punish its business-tortfeasors does not overcome Nebraska's most significant relationship and forum-court presumption.").

1 RESPECTFULLY SUBMITTED this 28th day of August, 2017. 2 s/Richard B. North, Jr. Richard B. North, Jr. 3 Georgia Bar No. 545599 Matthew B. Lerner 4 Georgia Bar No. 446986 NELSON MULLINS RILEY & SCARBOROUGH, LLP 5 Atlantic Station 201 17th Street, NW / Suite 1700 6 Atlanta, GA 30363 PH: (404) 322-6000 7 FX: (404) 322-6050 richard.north@nelsonmullins.com 8 matthew.lerner@nelsonmullins.com 9 James R. Condo (#005867) Amanda Sheridan (#027360) 10 SNELL & WILMER L.L.P. One Arizona Center 11 400 E. Van Buren Phoenix, AZ 85004-2204 12 PH: (602) 382-6000 jcondo@swlaw.com 13 asheridan@swlaw.com 14 Attorneys for Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. 15 16 17 18 19 20 21 22 23 24 25 26 27 28

CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of August 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr. Richard B. North, Jr.

REDACTED DOCUMENTS RELATED TO DOCKET 7341

7344 - Defendants' Separate Statement of Facts in Support of Motion for Partial Summary Judgment as to Plaintiff Carol Kruse's Claims - Filed Redacted

	1	James R. Condo (#005867) Amanda C. Sheridan (#027360)							
	2	SNELL & WILMER L.L.P. One Arizona Center							
	3	400 E. Van Buren, Suite 1900							
	4	Phoenix, AZ 85004-2204 Telephone: (602) 382-6000							
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	6	Richard B. North, Jr. (admitted pro hac vice)							
	7	Georgia Bar No. 545599 Matthew B. Lerner (admitted <i>pro hac vice</i>)							
	8	Georgia Bar No. 446986 NELSON MULLINS RILEY & SCARBOROUGH LI	LP						
	9	Atlantic Station 201 17th Street, NW, Suite 1700							
	10	Atlanta, GA 30363 Telephone: (404) 322-6000							
	11	richard.north@nelsonmullins.com matthew.lerner@nelsonmullins.com							
	12	Attorneys for Defendants C. R. Bard, Inc. and							
	13	Bard Peripheral Vascular, Inc.							
0.009-7	14	IN THE UNITED STATES DISTRICT COURT							
(404) 322-6000	15	FOR THE DISTRICT OF ARIZONA							
	16	IN RE: Bard IVC Filters Products Liability	No. 2:15-MD-02641-DGC						
	17	Litigation,	DEFENDANTS' SEPARATE						
	18		STATEMENT OF FACTS IN SUPPORT OF MOTION FOR						
	19		SUMMARY JUDGMENT AS TO PLAINTIFF CAROL KRUSE'S						
	20		CLAIMS						
	21		(Assigned to the Honorable David G.						
	22	CAROL KRUSE, an individual,	Campbell)						
	23	Plaintiff,							
	24	v.							
	25	C. R. BARD, INC., a New Jersey							
		and and and DADD DEDIDITED AT							
	26	corporation and BARD PERIPHERAL VASCULAR, INC., an Arizona							
	26 27	corporation and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation,							
		corporation and BARD PERIPHERAL VASCULAR, INC., an Arizona							

1	Pursuant to Fed. R. Civ. P. 56(c), Local Rule 56.1(a), and Case Management Order
2	No. 53 (Doc. 5770), Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.
3	(collectively "Bard") respectfully submit this Separate Statement of Facts in Support of
4	Motion for Summary Judgment as to Plaintiff Carol Kruse's Claims.
5	1. Plaintiff Carol Kruse . (Ex. A,
6	Fourth Supplemental Plaintiff Fact Sheet of Plaintiff Carol Kruse (hereinafter "PFS"), at
7	§ II.2(a).)
8	2. The Filter is not sold directly to patients. (Ex. B, G2 Filter Instructions for
9	Use (the "G2 IFU") at page 1.)
10	3. Plaintiff received her Filter
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12	. (Ex. C, Selected Plaintiff Medical Records.)
13	4. According to Plaintiff's implanting physician,
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15	(Ex. D, April 4, 2017 Dr. Shanon Smith
16	Deposition Transcript ("Smith Dep. Tr.") at 123:2-12.)
17	5. Plaintiff
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20	(Ex. C, Selected
21	Plaintiff Medical Records.)
22	6. Plaintiff testified that,
23	
24	(Ex. E, February 20, 2017 Carol Kruse Deposition Transcript ("Kruse Dep. Tr.) at 127:21
25	to 128:16.)
26	7. Plaintiff testified that
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28	(Ex. E, Kruse Dep. Tr. at 129:16 to

130:3; 134:4-17.)

- 8. Plaintiff testified that in 2009 or 2010, she saw TV advertisements soliciting potential IVC filter plaintiffs. (Ex. E, Kruse Dep. Tr. at 45:6-23.)
- 9. Plaintiff testified that she saw these TV advertisements soliciting potential IVC filter plaintiffs before she underwent her Filter removal procedure in April 2011. Ex. E, Kruse Dep. Tr. at 48:23 to 49:7.)
- 10. Plaintiff testified that, within "a couple of weeks" of seeing the TV advertisements soliciting potential IVC filter plaintiffs, she called the phone number she saw on the advertisement regarding her potential IVC filter claim. (Ex. E, Kruse Dep. Tr. at 45:24 to 46:15.)
- 11. Although it was "years" before she formally hired an attorney regarding her potential IVC filter lawsuit, Plaintiff testified that she periodically received letters regarding her "case" from a lawyer named Russell Button. (Ex. E, Kruse Dep. Tr. at 46:24 to 47:22.)
- 12. Plaintiff testified that she called her daughter shortly after seeing the TV advertisements regarding potential IVC filter lawsuits to discuss her IVC filter. (Ex. E, Kruse Dep. Tr. at 14:4-19.)

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13.
(Ex. C, Selected Plaintiff Medical Records.)
14.
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(Ex. C, Selected Plaintiff Medical Records.)

(Ex. C, Selected Plaintiff Medical Records.)

15.

(Ex. E, Kruse Dep. Tr. at 134:23 to 138:16.)

16. Plaintiff admits that

(Ex. A, PFS at § II.13(c).)

17. Dr. Smith testified that before he placed the Filter, he had the IFU that

accompanied	the	Filter	available	to	hım	to	read.	(Ex.	D,	Smith	Dep.	Tr.	at	152:25	to
153:6.)															
															_

- 18. The G2 IFU applicable in July 2009 (contains specific warnings regarding the risks of filter tilt, migration, fracture, perforation, and inability to retrieve. (Ex. B, G2 IFU.)
 - 19. Specifically, the IFU states as follows:
 - a. Under the bolded heading "**Potential Complications**," the G2 IFU reads as follows:
 - Movement or migration of the filter is a known complication of vena cava filters.
 - Filter fracture is a known complication of vena cava filters.
 - Perforation or other acute or chronic damage of the IVC wall.

* * *

All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ration for a patient who is at risk of pulmonary embolism without intervention.

(Ex. B, G2 IFU.)

- b. In the bolded "Clinical Experience" section, the IFU notes that in the clinical trial regarding the G2 Filter, "filter tilt" was observed 15 times, and that there were "3 technical failures for retrieval resulted from inability to engage the filter apex with the Recovery Cone® Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall." (Ex. B, G2 IFU.)
- c. Under the bolded "G2® Filter Removal" heading, the G2 IFU states in bolded language as follows:

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It is possible that complications such as those described in the "Warnings", "Precautions," and "Potential Complications" sections of this Instructions for Use may affect the recoverability of the device and result in the clinician's decision to have the device remain permanently implanted.

(Ex. B, G2 IFU.)

20. Dr. Smith testified that he was independently aware of the risks of filter tilt, migration, perforation, and fracture, and that

(Ex. D, Smith Dep. Tr.

at 100:2-14; 153:7-17.)

- 21. Dr. Smith testified that more information is helpful. (Ex. D, Smith Dep. Tr. at 181:16-20.)
- 22. Dr. Smith never testified that had he received some additional information from Bard, he would have used a different device with Plaintiff.
- 23. Dr. Smith testified that "it's possible" he would have changed his treatment of Plaintiff had he received some additional information from Bard about the G2 Filter. (Ex. D, Smith Dep. Tr. at 60:25 to 62:3.)
- 24. When asked whether the alleged facts and documents shown to Dr. Smith by Plaintiff's counsel would have changed his decision to use a G2 Filter with Plaintiff, Dr. Smith testified that he "wouldn't want to say how they would influence me without knowing what they say in detail." (Ex. D, Smith Dep. Tr. at 148:21 to 149:5.)
- 25. Dr. Smith testified that he relied on his training, experience, the experience of his colleagues, and the applicable medical literature when he makes treatment decisions regarding his patients, including Ms. Kruse. (Ex. D, Smith Dep. Tr. at 145:21 to 146:12.)
- 26. Dr. Smith did not testify that he relied on any statement by Bard, or any omission of material fact, in deciding to use the Filter.
 - (Ex. A, PFS at § II.11.)

1	28. Dr. Smith
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3	(Ex. D, Smith Dep. Tr. at 74:16-25.)
4	29. Plaintiff's vascular and interventional radiologist expert, Dr. Darren Hurst
5	testified that Plaintiff's Filter
6	(Ex. F, July 21, 2017 Dr. Darren Hurst Deposition Transcript at 159:1-11.)
7	30. On February 5, 2013, Plaintiff filed a Chapter 7 Bankruptcy Petition. (Ex
8	G, Carol Kruse Bankruptcy Case (Case No. 13-40196-TLS, U.S Bankruptcy Court
9	District of Nebraska (Lincoln Office)), Bankruptcy Petition ("Kruse Bankruptcy Petition)
10	Ex. E, Kruse Dep. Tr. at 187:8-20.)
11	31. In her Petition, Plaintiff filled out a Schedule in which she verified all of her
12	"personal property of whatever kind." (Ex. G, Kruse Bankruptcy Petition, Schedule E
13	- Personal Property.)
14	32. Under No. 21 ("Other contingent and unliquidated claims of every nature")
15	of Schedule B of her Bankruptcy Petition, Plaintiff marked an "X" for "NONE." (Ex. G
16	Kruse Bankruptcy Petition, Schedule B - Personal Property, No. 21.)
17	33. Under No. 35 ("Other personal property of any kind not already listed") of
18	Schedule B of her Bankruptcy Petition, Plaintiff marked an "X" for "NONE." (Ex. G
19	Kruse Bankruptcy Petition, Schedule B - Personal Property, No. 35.)
20	34. Plaintiff filled out "Schedule F - Creditors Holding Unsecured Nonpriority
21	Claims," in which she identified \$36,067.44 in such claims. (Ex. G, Kruse Bankruptcy
22	Petition, Schedule F - Creditors Holding Unsecured Nonpriority Claims.)
23	35. Plaintiff signed the Petition, declaring under penalty of perjury that the
24	information provided in the Petition is true and correct. (Ex. G, Kruse Bankruptcy Petition
25	at page 3 ("Signatures").)
26	36. On February 8, 2013, an Interim Trustee was appointed to Plaintiff's
27	bankruptcy estate. (Ex. H, Carol Kruse Bankruptcy Case (Case No. 13-40196-TLS, U.S.

Bankruptcy Court, District of Nebraska (Lincoln Office)), Notice of Chapter 7

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Bankrupicy Case, Meeting of Creditors, & Deadnnes.)
37. On April 1, 2013, after making a "diligent inquiry into the financial affairs'
of Plaintiff, the bankruptcy trustee declared that he did not "receive[] any property" for
the estate, and that "there is no property available for distribution," and he certified that
Plaintiff's estate has been fully administered. (Ex. I, Carol Kruse Bankruptcy Case (Case
No. 13-40196-TLS, U.S Bankruptcy Court, District of Nebraska (Lincoln Office)) Docker
Report ("Kruse Bankruptcy Docket Report") at No. 7.)
29 On June 2 2012 Plaintiff obtained a hankementary discharge ander (Ey. I

- On June 3, 2013, Plaintiff obtained a bankruptcy discharge order. (Ex. J, 38. Carol Kruse Bankruptcy Case (Case No. 13-40196-TLS, U.S Bankruptcy Court, District of Nebraska (Lincoln Office)), Discharge Order; Ex. E, Kruse Dep. Tr. at 187:24 to 188:16.)
- 39. As of the date of this filing, Plaintiff has not filed a motion to reopen her bankruptcy estate. (Ex. I, Kruse Bankruptcy Docket Report.)
- 40. Plaintiff testified that she never spoke to anyone at Bard. (Ex. E, Kruse Dep. Tr. at 187:1-3.)
- 41. Plaintiff testified that she never received any written or verbal information about her filter before she received it. (Ex. A, PFS at § II.8.)
- 42. Plaintiff testified that she never researched IVC filters. (Ex. E, Kruse Dep. Tr. at 87:25 to 88:5.)
- 43. Plaintiff testified that she did not know that Bard was the manufacturer of her Filter until the day she (Ex. E, Kruse Dep. Tr. 87:8-24.)

RESPECTFULLY SUBMITTED this 28th day of August, 2017.

s/Richard B. North, Jr. Richard B. North, Jr. Georgia Bar No. 545599 Matthew B. Lerner Georgia Bar No. 446986 NELSON MULLINS RILEY & SCARBOROUGH, LLP **Atlantic Station** 201 17th Street, NW / Suite 1700 Atlanta, GA 30363

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Attorneys for Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of August 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr. Richard B. North, Jr.

 $Nelson\ Mullins\ \underset{\tiny{LLP.\ Street NW.\ Surfer \ NW.\ Street \ NW.\ Suite}}{S01\ 17^{th}\ Street \ NW.\ Suite} \times Scarborough$

- 1 -

REDACTED DOCUMENTS RELATED TO DOCKET 7341

Exhibit A - Filed Redacted

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF ARIZONA

MDL No. 2641 In Re Bard IVC Filter Products Liability Litigation

PLAINTIFF FACT SHEET - Fourth Supp.

Each plaintiff who allegedly suffered injury as a result of a Bard Inferior Vena Cava Filter must complete the following Plaintiff Fact Sheet ("Plaintiff Fact Sheet"). In completing this Fact Sheet, you are <u>under oath and must answer every question</u>. You must provide information that is true and correct to the best of your knowledge. If you cannot recall all of the details as requested, please provide as much information as you can and then state that your answer is incomplete and explain why, as appropriate. If you select an "I Don't Know" answer, please state all that you do know about that subject. If any information you need to complete any part of the Fact Sheet is in the possession of your attorney, please consult with your attorney so that you can fully and accurately respond to the questions set out below. If you are completing the Fact Sheet for someone who cannot complete the Fact Sheet for himself/herself, please answer as completely as you can.

The Fact Sheet shall be completed in accordance with the requirements and guidelines set forth in the applicable Case Management Order. A completed Fact Sheet shall be considered interrogatory answers pursuant to Fed. R. Civ. P. 33 and responses to requests for production pursuant to Fed. R. Civ. P. 34 and will be governed by the standards applicable to written discovery under Fed. R. Civ. P. 26 through 37. Therefore, you must supplement your responses if you learn that they are incomplete or incorrect in any material respect. The questions and requests for production of documents contained in this Fact Sheet are non-objectionable and shall be answered without objection. This Fact Sheet shall not preclude Bard Defendants from seeking additional documents and information on a reasonable, case-by-case basis, pursuant to the Federal Rules of Civil Procedure and as permitted by the applicable Case Management Order.

In filling out this form, "healthcare provider" shall mean any medical provider, doctor, physician, surgeon, pharmacist, hospital, clinic, medical center, physician's office, infirmary, medical/diagnostic laboratory, or any other facility that provides medical care or advice, along with any pharmacy, x-ray department, radiology department, laboratory, physical therapist/physical therapy department, rehabilitation specialist, chiropractor, or other persons or entities involved in your diagnosis, care and/or treatment.

In filling out this form, the terms "You" or "Your" refer to the person who received a Bard Inferior Vena Cava Filter manufactured and/or distributed by C. R. Bard, Inc. or Bard Peripheral Vascular, Inc. ("Bard Defendants") and who is identified in Question 1(a) below.

To the extent that the form does not provide enough space to complete your responses or answers, please attach additional sheets as necessary, Information provided by Plaintiff will only be used for the purposes related to this litigation and may be disclosed only as permitted under the protective order in this litigation.

	I. BACKGROUND INFORMATION
Plea	se state:
(a)	Full name of the person who received the Bard inferior vena cava filter, including maiden name: Carol Dianne Kruse
(b)	List all names by which you have ever been known, if different from that listed in 1(a): Carol Dianne Jennings
	Carol Dianne Crouse
(c)	Full name of the person completing this form, if different from the person listed in
	1(a) above, and the relationship of the person completing this form to the person
	listed in 1(a) above:
(d)	The name and address of your primary attorney: Ben C. Martin/Thomas Wm. Arbon
	Law Offices of Ben C. Martin
	3710 Rawlins St., Suite 1230
	Dallas, TX 75219
(e)	When did you first retain an attorney to represent you in your lawsuit against Bard? On or about July 3, 2013
You	r Social Security Number:
	r Date of Birth:
You	r current residential address:
If yo	ou have lived at this address for less than 10 years, provide each of your prior
resid	lential addresses from 2000 to the present:
	Prior Residential Address Dates You Lived At This Address

II. CLAIM INFORMATION 1. Have you ever received a Bard Inferior Vena Cava Filter? Yes No If Yes, please check the box(es) for each type of Bard Inferior Vena Cava Filter yo received: Recovery® G2®X	
If Yes, please check the box(es) for each type of Bard Inferior Vena Cava Filter yo received: Recovery® G2®	
✓ G2®	u have
G2®X	
G2®Express	
Eclipse®	
Meridian®	
Denali®	
Simon Nitinol	
Other (please identify):	
2. For each Bard Inferior Vena Cava Filter identified above, please provide the follow	ving
information:	
(a) The date each Bard Inferior Vena Cava Filter was implanted in you:	

(b)	The product code and lot number of each Bard Inferior Vena Cava Filter implanted in you:
(c)	Current location of the Bard Inferior Vena Cava Filter, including any portion
	thereof, if known:
Desc	ribe your understanding of the medical condition for which you received the Bard
Infer	ior Vena Cava Filter(s):
	the name and address of the doctor who implanted the Bard Inferior Vena Cava
Give Filter	
Filter	r(s):
Filter Give	the name and address of the hospital or other healthcare facility where the Bard
Filter Give	r(s):
Give	the name and address of the hospital or other healthcare facility where the Bard for Vena Cava Filter was implanted:
Give Inferi	the name and address of the hospital or other healthcare facility where the Bard for Vena Cava Filter was implanted: you ever been implanted with any other vena cava filters or related product(s)
Give Inferi	the name and address of the hospital or other healthcare facility where the Bard for Vena Cava Filter was implanted: you ever been implanted with any other vena cava filters or related product(s) es the Bard Inferior Vena Cava Filter(s) for the treatment of the same or similar
Give Inferior Have besid condi	the name and address of the hospital or other healthcare facility where the Bard for Vena Cava Filter was implanted: you ever been implanted with any other vena cava filters or related product(s) es the Bard Inferior Vena Cava Filter(s) for the treatment of the same or similar ition(s) identified in your response to question 3 above? Yes
Give Inferior Have beside conditions of the cond	the name and address of the hospital or other healthcare facility where the Bard for Vena Cava Filter was implanted: you ever been implanted with any other vena cava filters or related product(s) es the Bard Inferior Vena Cava Filter(s) for the treatment of the same or similar ition(s) identified in your response to question 3 above? Yes
Give Inferior Have beside conditions of the cond	the name and address of the hospital or other healthcare facility where the Bard for Vena Cava Filter was implanted: you ever been implanted with any other vena cava filters or related product(s) es the Bard Inferior Vena Cava Filter(s) for the treatment of the same or similar ition(s) identified in your response to question 3 above? Yes
Give Inferi Have besid condi	the name and address of the hospital or other healthcare facility where the Bard for Vena Cava Filter was implanted: you ever been implanted with any other vena cava filters or related product(s) es the Bard Inferior Vena Cava Filter(s) for the treatment of the same or similar ition(s) identified in your response to question 3 above? Yes
Give Inferior Have beside conditions of the cond	the name and address of the hospital or other healthcare facility where the Bard for Vena Cava Filter was implanted: you ever been implanted with any other vena cava filters or related product(s) es the Bard Inferior Vena Cava Filter(s) for the treatment of the same or similar ition(s) identified in your response to question 3 above? Yes
Give Inferi Have besid condi	the name and address of the hospital or other healthcare facility where the Bard for Vena Cava Filter was implanted: you ever been implanted with any other vena cava filters or related product(s) es the Bard Inferior Vena Cava Filter(s) for the treatment of the same or similar ition(s) identified in your response to question 3 above? Yes

	(d)	o was the physician who implanted this other device or product?		
	(e)	At what hospital or facility was this other device or product implanted in you?		
	(f)	Why was this other device or product implanted in you?		
7.		than the Bard Inferior Vena Cava Filter device that is the subject of your lawsuit or		
		ified in response to question 6 above, are you aware of any other Vena Cava Filter(s) anted inside your body at any time? Yes No		
	If yes	, please provide the following information:		
	(a)	Product name:		
	(b)	Date of procedure placing it and name and address of doctor who placed it:		
	(c)	Condition sought to be treated through placement of the device:		
	(d)	Any complications you encountered with the medical product or procedure:		
	(e)	Does that product remain implanted inside of you today? Yes No		
8.	and/o	to implantation with a Bard Inferior Vena Cava Filter, did you receive any written r verbal information or instructions regarding the Bard Inferior Vena Cava Filter, ding any risks or complications that might be associated with the use of the same? No. Don't Know. Provide the date you received the written and/or verbal information or instructions:		

	(b)	Identify by name and address the person(s) who provided the information and instructions:
	(c)	What information or instructions did you receive?
	(d)	If you have copies of the written information or instructions you received, please attach copies to your response.
	(e)	Were you told of any potential complications from the implantation of the Bard Inferior Vena Cava Filter(s)? Yes No Don't Know
	(f)	If yes to (e), by whom?
	(g)	If yes to (e), what potential complications were described to you?
9.	Do yo Yes If Yes	No Don't Know Don't Know
	(a)	Has any doctor recommended removal of the Bard Inferior Vena Cava Filter(s)? Yes No Inferior Vena Cava Filter(s)? If Yes:
		(i) Identify by name and address every doctor who recommended removal of the Bard Inferior Vena Cava Filter(s):
		(ii) For each doctor identified in response to question 8(a)(i) above, state your understanding of why the doctor recommended removal

		(iii)	For each doctor identified in response to question 8(a)(i) above, state when the doctor recommended removal.
10.	Has the part?	ne Bard I	Inferior Vena Cava Filter(s) implanted in you been removed, in whole or in No. Don't Know
	If Yes	:	
	(a)		, when, and by whom was the Bard Inferior Vena Cava Filter(s), or any of it, removed?
	(b)	-	portion of the Bard Inferior Vena Cava Filter(s) was removed on the date ed in response to question 9(a) above?
	(c)	Please	check <u>all</u> that apply regarding the removal procedure(s): Removed percutaneously Removed via an open abdominal procedure
			Removed via an open chest procedure Other, Describe: Unknown
	(d)	you? If Yes,	ny portion of the Bard Inferior Vena Cava Filter(s) remain implanted in Yes No Don't Know explain what portion of the Bard Inferior Vena Cava Filter(s) you believe implanted in you:

	(e)	Explain why you consented to have the Bard Inferior Vena Cava Filter(s), or any portion thereof, removed?				
	40					
	(f)	Does any medical provider, physician, entity, or anyone else acting on your behalf				
		have possession of any portion of the Bard Inferior Vena Cava Filter that was				
		previously implanted in you and subsequently removed?				
		Yes No Don't Know				
		If Yes, please state the name and address of the person or entity having possession				
		of same				
11.	Has a	any doctor or healthcare provider unsuccessfully attempted to remove the Bard				
	Infer	ior Vena Cava Filter(s) implanted in you?				
	Yes	No_ Don't Know				
	If Ye	s:				
	(a)	How many attempts have been made to remove the Bard Inferior Vena Cava				
		Filter(s) implanted in you?				
	(b)	Provide the name and address of the doctor who removed (or attempted to				
		remove) the filter strut(s) and the hospital or medical facility at which it was				
		removed (or attempted to be removed).				
		Filter Removal/Attempted Removal #1				
		Doctor				
		Hospital/Medical Facility:				
		Date				
		Filter Removal/Attempted Removal #2				
		Doctor:				
		Hospital/Medical Facility:				
		Date:				
		Filter Removal/Attempted Removal #3				

			Doctor:
			Hospital/Medical Facility:
			Date:
	(c)	Please	check <u>all</u> that apply regarding attempted removal procedure #1:
			Attempted but unsuccessful percutaneous removal procedure
			Attempted but unsuccessful open abdominal procedure
			Attempted but unsuccessful open chest procedure
			Other, Describe:
			Unknown
	(4)	Dlease	check <u>all</u> that apply regarding attempted removal procedure #2:
	(d)	Tiease	
			Attempted but unsuccessful percutaneous removal procedure
			Attempted but unsuccessful open abdominal procedure
			Attempted but unsuccessful open chest procedure
			Other, Describe:
			Unknown
	(e)	Please	check <u>all</u> that apply regarding attempted removal procedure #3:
	` '		Attempted but unsuccessful percutaneous removal procedure
			Attempted but unsuccessful open abdominal procedure
			Attempted but unsuccessful open chest procedure
			Other, Describe:
			Unknown
12.	Do yo	ou claim	that your Bard Inferior Vena Cava Filter(s) fractured?
	Yes		No

If Yes:	
(i)	Please state the number of fractured struts retained in your body?
(ii)	Please identify the location(s) within your body of each retained filter strut.
(iii)	Please provide the date or approximate date when you were first informed of each fractured strut.
(iv)	Has any health care provider recommended to you that a retained filter strut(s) should be removed? Yes No D If Yes, provide the name and address of any such healthcare provider, as well as the approximate date on which the communication occurred.
(v)	Has any health care provider recommended to you that a retained filter strut should <u>not</u> be removed? Yes No No The strutter of the structure
(vi)	Have any fractured struts been removed, or attempted to have been removed, from your body? Yes No

	If Ye	s:
	(1)	If any fractured filter strut has been removed (or a doctor has
		attempted to remove any strut), please check all that apply
		regarding the removal/attempted removal procedure(s):
		Removed percutaneously
		Removed via an open abdominal procedure
		Removed via an open chest procedure
		Attempted but unsuccessful percutaneous removal
		procedure
		Attempted but unsuccessful open abdominal procedure
		Attempted but unsuccessful open chest procedure
		Other, Describe:
		Unknown
	(2)	Provide the name and address of the doctor who removed (or
	(-)	attempted to remove) the <u>filter strut(s)</u> and the hospital or medical
		facility at which it was removed (or attempted to be removed).
		Filter Strut Removal/Attempted Removal #1
		Doctor:
		Hospital/Medical Facility:
		Date:
		Filter Strut Removal/Attempted Removal #2
		Doctor:
		Hospital/Medical Facility:
		Date:
13.	Do you claim that y	ou suffered bodily injuries as a result of the implantation of the Bard
	Inferior Vena Cava	Filter(s)? Yes No
	If Yes:	

of the Bard	m resulted from the implantation, attempted removal and/or removal
When was th	
When was th	
When was th	
	he first time you experienced symptoms of any of the bodily injuries
you claim in	your lawsuit to have resulted from the Bard Inferior Vena Cava
Filter(s)?	
When did yo	ou first attribute these bodily injuries to the Bard Inferior Vena Cava
Filter(s)?	
To the best of	of your knowledge and recollection, please state the approximate date
when you fir	rst saw a health care provider for any of the bodily injuries, or
symptoms re	elated thereto, you claim to have experienced related to the Bard
Inferior Ven	a Cava Filter(s)?
To the best of	of your knowledge and recollection, has any health care provider eve
told you oral	lly or in writing that any symptoms related to bodily injury are relate
to the Bard I	Inferior Vena Cava Filter(s)?
Yes	No
If Vac alone	se state the name and address of any such health care provider, as wel
m res, pieas	
, ,	the approximate date the statement was made, and provide the detail

VERIFICATION

I, Carol Dianne Kruse	, declare under penalty of perjury, subject to all applicable
laws and in the presence of the	below named witness, that I have carefully reviewed the final
copy of this Plaintiff Fact Sheet	
provided is true and correct to the	e best of my knowledge, information and belief.
	2
- m 1	
De GMeDona	_ Coul D. Truse
Signature of Witness	Signature of Plaintiff
Daniel J. MacDonald	
Name of Witness	

Address of Witness

REDACTED DOCUMENTS RELATED TO DOCKET 7341

Exhibit C - Filed Redacted

EXHIBIT C

ne

REDACTED DOCUMENTS RELATED TO DOCKET 7341

Exhibit D - Filed Redacted

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1
                  UNITED STATES DISTRICT COURT
 2
                             FOR THE
 3
                       DISTRICT OF ARIZONA
 4
     In Re BARD IVC FILTERS PRODUCTS
 5
    LIABILITY LITIGATION
 6
                       No. MD-15-02641-PHX-DGC
     and
 8
 9
     CAROL KRUSE
                                 )MDL No. 2641
10
                      Plaintiff,)
11
                VS.
    C.R. BARD AND BARD
12
    PERIPHERAL VASCULAR, INC., )
13
                      Defendant.)
      * * * * * * * * * * * * * *
14
           DO NOT DISCLOSE - SUBJECT TO FURTHER
15
                CONFIDENTIALITY REVIEW
16
    VIDEOTAPED DEPOSITION OF: SHANON SMITH, M.D.
17
    DATE: April 4, 2017
18
    TIME: 2:00 p.m.
19
     PLACE: Mary Lanning Memorial Hospital, 15 North St.
     Joseph Avenue, Hastings, Nebraska
20
21
22
23
24
25
```

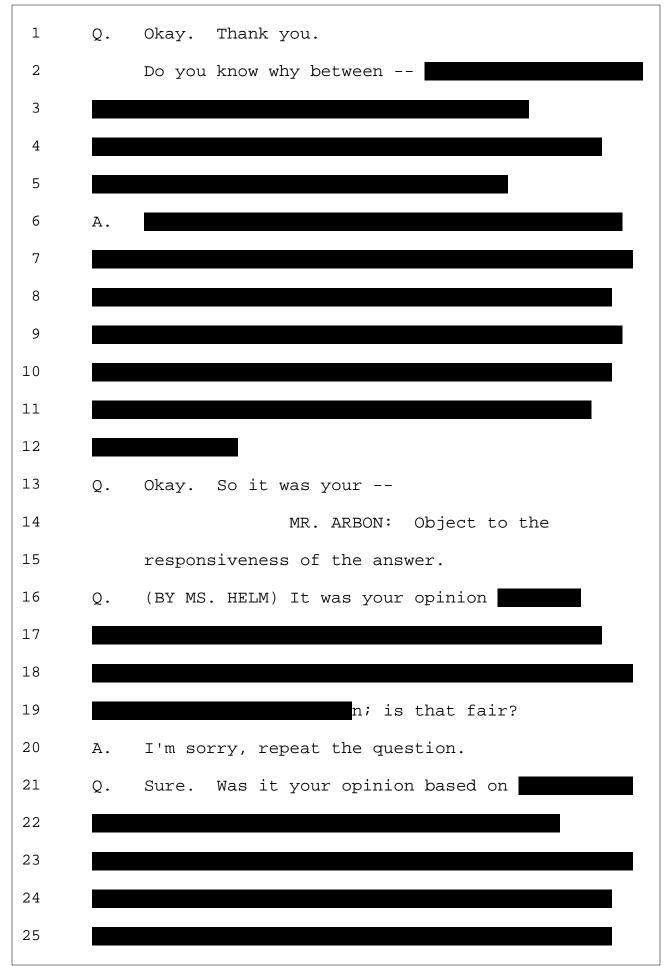
- filter had more of a tendency to cause complications
- than its -- than its Recovery filter?
- MS. HELM: Object to the form.
- 4 A. Say that one more time.
- 5 Q. (BY MR. ARBON) Yeah. Does it surprise you to
- 6 see that Bard had data that demonstrated the G2
- 7 filter that you implanted in Ms. Kruse had more --
- 8 higher complication rate concerning migration, tilt
- 9 and perforation, than its predecessor the Recovery
- 10 filter?
- MS. HELM: Object to the form.
- 12 A. I wouldn't have known what they had at the time.
- Q. (BY MR. ARBON) And I'm not asking you about at
- the time, because I know you didn't have that
- 15 information. You had no such information --
- 16 A. No.
- 17 Q. -- when you chose the G2, did you?
- 18 A. Right, correct.
- 19 Q. If you had that information when you were making
- decisions as to what to implant, do you know if you
- would have chosen that G2?
- MS. HELM: Object to the form.
- 23 A. I would have definitely looked at the risk and
- 24 benefits if there was more information.
- Q. (BY MR. ARBON) And if Bard's data is correct

- that the G2 prevented a higher risk of migration, a
- 2 higher risk of perforation and a higher risk of tilt,
- do you think you would have chosen that if that
- 4 information would have been available to you?
- 5 MS. HELM: Objection to the form.
- 6 A. Now, you made a big claim, so I assume that
- 7 claim is correct, you know, of these higher
- 8 percentages. And that would be true in every case.
- 9 So, assuming that's a correct statement, the -- yeah,
- 10 I would want to know if one product had different
- 11 numbers relative to another product.
- 12 Q. (BY MR. ARBON) Well, specific to the G2 numbers
- that I've shown you. If, assume for me those that,
- 14 that data that Bard gave us is accurate --
- 15 A. Okay.
- 16 Q. -- and you had that information back in --
- 17 A. Right.
- 18 Q. -- 2009 when you were making the decision to put
- 19 this G2 into Ms. Kruse, would that type of data
- 20 affected that decision?
- MS. HELM: Object to the form.
- 22 A. I would have definitely used that information
- and whatever else to make a decision.
- Q. (BY MR. ARBON) Okay. And had you had the
- benefit of that information, you may have chosen a

- device other than a G2; is that true?
- MS. HELM: Object to the form.
- 3 A. It's possible.
- 4 Q. (BY MR. ARBON) Let's go to the implant, Doctor.
- 5 A. Because then I wouldn't be meeting with you.
- 6 MS. HELM: I got to move to strike
- 7 that off the record.
- 8 THE WITNESS: That's fine. I'm
- 9 not sure how to answer that.
- 10 (Discussion off the record.)
- 11 (Exhibit No. 2115, marked for identification.)
- 12 Q. (BY MR. ARBON) I'm going to hand you what I've
- marked as 2115, Doctor, and ask you if you recognize
- 14 that document?
- 15 A. Yes, 2115.
- 16 Q. And is there a Bates number at the bottom of
- 17 that page?
- 18 A. There's a number.
- 19 Q. Okay. Can you read that for me.
- MS. HELM: You can just read --
- 21 A. 00288.
- MS. HELM: That's fine.
- O. (BY MR. ARBON) Okay.
- 24 A. Okay.
- Q. And do you recognize that document, sir?

1 I saw that. Α. 2 Q. Okay. And that's what you were attempting to do; is that correct? 3 4 That's correct. 5 Q. Were you trying to follow the instructions for use that Bard had provided for recovering a G2 6 7 filter? MS. HELM: Object to the form. 8 I was recovering the way I had been trained. 9 Α. 10 Q. (BY MR. ARBON) 11 12 Α. 13 Q. 14 15 Α. 16 Q. 17 Α. 18 19 Q. And when you say, 20 21 Α. 22 Q. 23 24 25

- 1 A. I know it's a possible for filters.
- Q. (BY MR. ARBON) Migration -- or I'm being very
- 3 specific about caudal migration.
- 4 A. I've been trained that they can migrate.
- 5 Q. And I guess that's specifically my point here,
- 6 sir. Because it's important 'cause that's the
- 7 condition we're facing.
- 8 Were you in your training more or less advised
- 9 that filters can migrate, that they can move?
- 10 A. Normally we taught that they tilt. That's the
- one thing that you're taught. But there are other
- complications that can occur, they can break, they
- can move, they can penetrate, other bad things can
- happen.
- 15 Q.
- 16
- 17
- 18 A.
- 19
- Q. How many filters do you believe you've placed
- since your fellowship?
- 22 A. Several.
- Q. Can you give me an estimate of how many is
- 24 several?
- 25 A. Between 10 and 20.



- 1
- Q. (BY MS. HELM) Have you seen commercials on
- 3 television placed by plaintiff's attorneys
- 4 advertising about IVC filters?
- 5 MR. ARBON: Objection to form.
- 6 A. I have.
- 7 Q. (BY MS. HELM) Do you have a filter? If you have
- 8 a filter, you might be entitled to compensation.
- 9 Call this number. Have you seen those kind of adds?
- 10 A. I think I have.
- MR. ARBON: Objection to form.
- 12 Q. (BY MS. HELM) Okay. Are you aware that dozens
- of Bard witnesses have had their depositions taken
- about Bard's documents and actions they took relating
- to their IVC filters?
- 16 A. I don't know what's happened outside this room.
- 17 Q. Okay. Plaintiff's counsel didn't show you any
- of that testimony today, did he?
- 19 A. I didn't -- I haven't seen anything other than
- what's presented so far.
- 21 Q. Okay. And when it comes to making decisions for
- 22 your patients and weighing the risks and benefits of
- medical devices that you use with your patients, you
- rely on a number of sources, don't you?
- 25 A. Yes.

- 1 Q. You rely on your training and experience?
- MR. ARBON: Objection, form.
- 3 A. Yes.
- 4 Q. (BY MS. HELM) You rely on your colleague's
- 5 experiences with certain products?
- MR. ARBON: Objection, form.
- 7 A. Yes.
- 8 Q. (BY MS. HELM) You rely on available medical
- 9 literature; is that right?
- MR. ARBON: Objection, form.
- 11 A. I rely my decision based on multiple sources and
- journal articles is one.
- Q. (BY MS. HELM) Okay. And you're not interested
- in getting unreliable information or data?
- 15 A. Not usually.
- 16 Q. Okay. Because getting unreliable information or
- data could adversely impact your risk benefit
- analysis; is that right?
- 19 A. Good data is the best data.
- 20 Q. And in making your treatment decisions for your
- 21 patients, you don't rely on internal information from
- internal documents of manufacturers of medical
- devices, do you?
- MR. ARBON: Objection, form.
- 25 A. That's not a common process.

- do whatever is appropriate --
- Q. (BY MS. HELM) Okay.
- 3 A. -- to figure out effectiveness and safetyness
- 4 (sic).
- 5 Q. Are you familiar with what is called the 510K
- 6 process for clearance of a product?
- 7 A. Not, not well.
- 8 Q. Okay. But are you familiar that there's a
- 9 process where a product such as a Bard filter is
- 10 cleared for use without going through randomized
- 11 clinical studies.
- 12 A. I wouldn't know that.
- Q. Okay. Do you rely on information from the FDA
- in making a risk benefit analysis to -- regarding
- 15 products you're going to use with your patients?
- 16 A. Well --
- MR. ARBON: Objection, form.
- 18 A. -- if medication has a black box FDA warning,
- 19 that would affect my treatment and I'm assuming for
- other products as well.
- Q. (BY MS. HELM) Okay. Is it fair to say that
- those first four exhibits that came from Bard were
- represented to you as Bard documents, you can't
- comment as to whether -- how those impacted or would
- 25 have impacted your decision to use the G2 filter in

- 1 Ms. Kruse?
- MR. ARBON: Objection, form.
- 3 A. Those are the first time I seen the documents.
- 4 I wouldn't want to say how they would influence me
- without knowing what they say in detail.
- 6 Q. (BY MS. HELM) And the context in which they were
- 7 created?
- 8 A. I'm sure my opinion would need to be based on a
- 9 lot of things.
- 10 Q. Okay. Fair.
- 11 A. Sorry for being vague on that.
- 12 Q. No, that's quite all right. It's quite all
- 13 right.
- You would expect companies such as Bard to
- 15 continue to assess their products by looking at
- complications and how the product's performing once
- it's in the market; would you not?
- MR. ARBON: Objection, form.
- 19 A. I would assume there's some post market process.
- Q. (BY MS. HELM) Okay. And would you also assume
- 21 that Bard would undertake some sort of a formal
- 22 process to evaluate those complications or events
- that occur once it's in the market?
- 24 MR. ARBON: Objection, form.
- 25 A. I wouldn't know what Bard would do in the normal

- 1 Q. (BY MS. HELM) Is that right?
- 2 A. Let's see, migration is written down.
- Q. Okay. And if you look again on Page 4 under the
- 4 bar chart, under the clinical experience -- it says
- 5 clinical experience at the top of the page and then
- 6 below the bar chart it indicates, "Asymptomatic
- 7 complications included caudal migration, " correct?
- 8 A. That's correct, that's written down.
- 9 Q. So this IFU or package insert as you call it, in
- it Bard indicated that migration and specifically
- caudal migration of the G2 filter were a risk; is
- 12 that right?
- 13 A. Yes, that's written down as a caudal migration
- is on this package insert, assuming it was in the box
- 15 at -- on that date.
- 16 Q. And the same thing as tilt, correct?
- MR. ARBON: Objection to form.
- 18 A. Let let's see, tilt is...
- 19 Q. (BY MS. HELM) Right above it it says, of the 61
- retrievals, it says remember, "Resulted from
- inability to engage the filter apex with the Recovery
- 22 Cone removal system due to filter tilt."
- 23 A. That's correct.
- Q. Okay. Okay.
- 25 And again, I understand you have to say assuming

- this was in the box, but assuming that this is the
- 2 IFU or package insert that accompanied the filter
- 3 that you implanted in Ms. Kruse in 2009, you had the
- 4 opportunity to review this IFU or package insert
- 5 before you did the implant, correct?
- 6 A. Correct.
- 7 Q. Okay. You were also aware of risks of the IVC
- 8 filters from your training --
- 9 A. Yes.
- 10 Q. -- and fellowship, correct?
- 11 A. Yes, because we already had one tilt that I was
- involved with.
- Q. Right, in your fellowship?
- 14 A. Correct.
- 15 Q. So you knew
- 16
- 17 A.
- 18 Q.
- 19 A.
- 20
- MR. ARBON: Objection, form and
- responsiveness.
- Q. (BY MS. HELM) Okay. You understand that Bard
- sales reps are not necessarily medically trained,
- 25 correct?

1 Doctor, 2 3 4 5 6 7 8 correct? 9 Object to the form. MS. HELM: 10 11 MR. ARBON: I'll pass. 12 MS. HELM: I have very couple 13 follow-ups. 14 CROSS EXAMINATION 15 BY MS. HELM: 16 Doctor, I'm not going to take you through the 17 IFU again, but you would agree with me that it's 18 important for you to read the entire IFU; would you 19 not? 20 Α. Yes, I think more information would be helpful. 21 Okay. And we discussed previously that in the Q. 22 clinical experience section of the IFU, it 23 specifically addressed caudal migration and tilt, 24 correct? 25 Α. The IFU has the word migration in it and I think

REDACTED DOCUMENTS RELATED TO DOCKET 7341

Exhibit E - Filed Redacted

EXHIBIT E



Deposition of: Carol Kruse

In the Matter of:

In Re: Bard IVC Filters Products Liability

Veritext Legal Solutions

1075 Peachtree St. NE , Suite 3625 Atlanta, GA, 30309 800.808.4958 | calendar-atl@veritext.com | 770.343.9696

	Page 14
1	sometime this year?
2	A. If not this year, real close to the end of
3	last year, yes.
4	Q. Before that conversation with your
5	daughter, had you spoken with your daughter about
6	your lawsuit against Bard regarding your IVC filter?
7	A. The only thing I had visited with her
8	about was way back when I, you know, called a number
9	that was on TV that said if you've had, you know, a
10	clot filter put in, call this number.
11	Q. So you saw that TV advertisement, and you
12	spoke you then spoke with your daughter?
13	A. I'm sure I didn't call her that day, you
14	know.
15	Q. But near that time you spoke with your
16	daughter about
17	A. Yes.
18	Q the advertisement you saw?
19	A. Yes.
20	Q. In any of the strike that.
21	With the discussion you had with your
22	daughter recently about the fact that she was going
23	to be deposed and you were going to be deposed, did
24	you at any point talk with her about the questions
25	that you might get asked?

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	Page 45
1	after you got the box?
2	A. Probably.
3	Q. And you filed your lawsuit on April 6,
4	2015; right? Does that sound right?
5	A. I don't know.
6	Q. Okay. Let's go back to Page to
7	Exhibit 5 for a moment, please.
8	And if you would look at Page 5, please.
9	At the top on question No. 14, it asks,
L 0	"Before contacting an attorney regarding this
L1	lawsuit or claim, had you ever seen a television or
L 2	print advertisement regarding possible claims
L 3	against Inferior Vena Cava Filter manufacturers,"
L 4	and you marked "yes."
L 5	A. Yes, uh-huh.
L 6	Q. Read for me the response. It asks for the
L 7	approximate date and nature of the advertisement.
L 8	What is your response there?
L 9	A. "I remember seeing the ad on TV about
20	people having IVC filters, and there was a telephone
21	number to call."
22	As far as approximate date, it would have
23	to be maybe 2010, 2009, somewhere in there.
24	Q. Do you know approximately between the time
25	that you saw the TV advertisement and when you

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	Page 46
1	called the number? Do you know how long in between?
2	A. I saw the advertisement in the evening. I
3	knew I couldn't call that day because they were
4	probably closed. And with my work schedule, you
5	know, I couldn't very well say, pardon me, I have to
6	make a phone call.
7	I don't know. I imagine it was, you know,
8	a couple weeks down the road maybe.
9	Q. I'm sure you could have called Tom at
10	midnight and he would have picked up.
11	A. Well
12	Q. So but your testimony it was probably a
13	couple weeks in between seeing the advertisement and
14	calling that number; correct?
15	A. Yeah.
16	MR. ARBON: Objection. Form. But go
17	ahead.
18	BY MR. NASH:
19	Q. Do you remember when you made that phone
20	call, who you spoke with?
21	A. No.
22	Q. Between making that phone call strike
23	that.
24	How long was it between the time you made
25	that phone call and the time you hired Mr. Arbon and

	Page 47
1	Mr. MacDonald here as your attorneys?
2	A. A while.
3	Q. And when you say "a while," are you able
4	to give us
5	A. Years. Every once in a while I would get
6	a letter from a company in Dallas that says, you
7	know, we haven't forgotten you, we are still working
8	on the case, and we will keep you informed.
9	Q. When you say the "company in Dallas," do
L O	you remember the name of the company?
L1	A. I don't have any of those letters.
L 2	Q. You didn't keep any of those letters from
L 3	that company?
L 4	Is that a "no"?
L 5	A. That's a no.
L 6	Q. Do you know if it was a law firm or
L 7	lawyers that were sending you those letters?
L 8	A. I believe it was a law firm. I remember a
L 9	name, but I have not talked, you know, to him or
20	received any letters for maybe two years.
21	Q. And what was that name that you remember?
22	A. That name was Russell Button.
23	MR. ARBON: And now that brings me
24	into the picture. I want you to be very cautious.
25	Russell Button was an attorney with our firm. You

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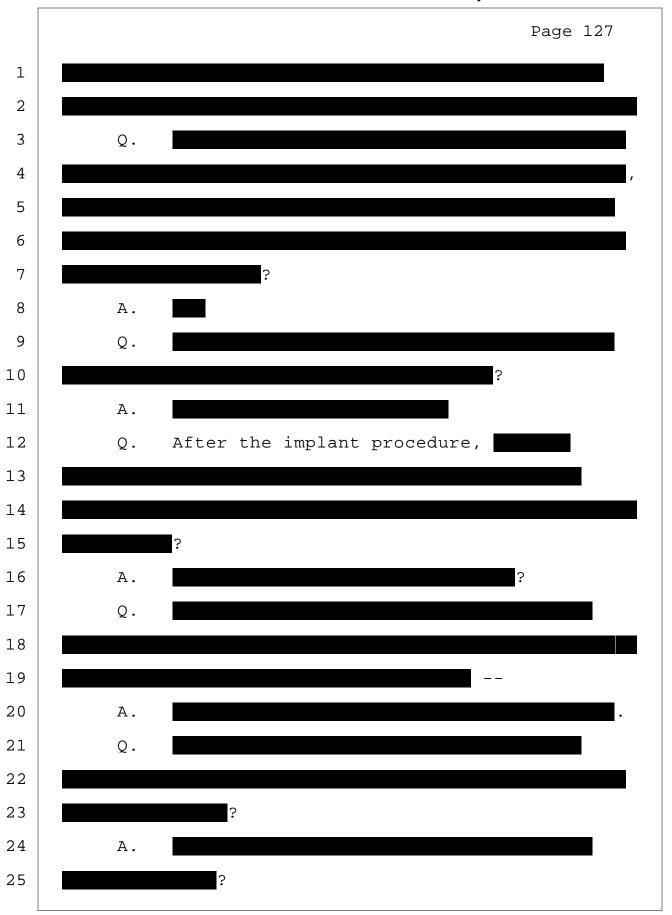
Page 48 are not going to discuss any communications you had 1 2. with him or any letters or what was the content of 3 any of those letters. That's attorney/client 4 privilege. 5 I just wanted to make sure we're talking 6 about what I thought we were talking about. 7 MR. NASH: And I didn't know. certainly don't want to --8 9 MR. ARBON: I'm not saying you did 10 anything wrong. Until we established where we were 11 headed with that, I didn't want to interject, but 12 now I'm interjecting. 13 BY MR. NASH: 14 And, Ms. Kruse, let me make sure it's Ο. 15 clear. 16 When I ask a question about anyone you've 17 talked with, if you've talked with an attorney, I'm 18 not interested -- well, I am interested, but I don't 19 want you to answer that. 20 Right. I did not actually talk to him. Α. Ι 21 did not actually talk to anybody there. All I got 2.2 was letters. 23 Do you remember seeing that TV advertisement before you had your procedure to 24 2.5 remove your filter?

	Page 49
1	A. Yes.
2	Q. Do you remember the content or substance
3	of that TV advertisement?
4	A. It was just a general you know, didn't
5	have any pictures or anything like that. Just, you
6	know, if you've had an IVC filter placed and have
7	had, you know, problems, please call this number.
8	Q. I'm going to mark or ask you to mark
9	for Exhibit 7, please.
10	(Exhibit No. 7
11	marked for identification.)
12	MR. NASH: Tom, this is just the
13	notice or amended notice.
14	BY MR. NASH:
15	Q. Ms. Kruse, I've you've been handed
16	Exhibit No. 7, and it if you read the title, it
17	says, "Amended Notice of Videotape Deposition Duces
18	Tecum of Carol Kruse."
19	Do you see that?
20	A. No, I do not.
21	Q. I'm sorry, flip to the first page of
22	what I'm sorry.
23	A. I was going to say, "No, I don't see
24	that."
25	Q. You are on the first page.

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1	A. No.
2	Q. Let's shift gears a little bit and talk
3	about this lawsuit and about the filter that you
4	have.
5	Do you know the model of the filter that
6	you received?
7	A. No.
8	Q. When did you first learn of who the
9	manufacturer was of the filter you received?
10	A. The day that they tried to take it out.
11	Q. And who do you understand to be the
12	manufacturer of your filter?
13	A. Bard. I wrote it down on you didn't
14	copy the back of this little thing, did you?
15	It was there. 5-milligram Bard. No, I
16	guess I wrote it down on but it must have been
17	on the another portion of it.
18	Q. But your testimony is that when you
19	received that piece of the box, you wrote down
20	"Bard"?
21	A. Yes.
22	Q. And at that time you knew who manufactured
23	your filter?
24	A. Right.
25	Q. Did you before at any point, have you

Page 88 ever done any research, whether it be online or at a 1 2 library, about IVC filters? 3 Α. No. Have you ever Googled IVC filters? 4 Q. 5 Α. No. Do you own a computer? 6 Q. 7 Α. No. 8 Go back to the Q. 9 We've already talked about it a little bit. 10 11 At that time, -12 13 14 15 Α. 16 And you testified since that time 17 Q. 18 ; correct? 19 Α. Correct. 20 Q. 21 ? 22 Α. 23 Q. 24 25 Α.

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1	Q. Yes.
2	A. I would imagine when I was doing physical
3	therapy.
4	Q. And was this when was your physical
5	therapy?
6	A. Three days after I had my knee put in or
7	the knee replaced.
8	Q. So you remember experiencing abdominal
9	pain within a few days after you received your IVC
10	filter?
11	A. Correct.
12	Q. And is it your testimony that you now
13	believe that abdominal pain was being caused by your
14	IVC filter?
15	A. Yes. I did not have that pain or
16	experience prior to the filter placement.
17	Q. Did you talk to your doctors about the
18	abdominal pain back just a few days after you
19	received your IVC filter?
20	A. I visited with him about it, and it was,
21	according to one of the doctors, probably some gas.
22	And so, I mean, nobody really, you know,
23	investigated because it didn't happen all the time.
24	It was just at certain times.
25	Q. Were you given any instructions by any of

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1	your doctors about any physical limitations you
2	might have as a result of receiving an IVC filter?
3	A. The only limitations were while you have
4	the dressing on, do not do any heavy lifting, you
5	know, or squatting, that sort of stuff.
6	Q. Were you given any other instructions
7	about your IVC filter after you had it in place?
8	A. No.
9	Q. Did you talk to any doctor about having it
10	periodically checked or reviewed?
11	A. No.
12	Q. Before April 2011 when you had your
13	retrieval attempt, did you ever go to a doctor to
14	have someone examine your IVC filter?
15	A. No.
16	Q. When is the first time you remember
17	speaking to a doctor about having your IVC filter
18	removed after it was implanted?
19	A. That would have been her name is Kristi
20	Eggers, and she was the nurse practitioner of the
21	little town of Sutton, and she came to the nursing
22	home where I was working.
23	And in our conversation I told her that I
24	had a filter, and, you know, I had this infrequent
25	pain, and she said, "Well, you know, can you have

	Page 130
1	the filter removed?" And that's kind of how we kind
2	of got to talking about it. So I called Dr. Smith
3	and said let's see if we can get it out.
4	Q. You said her name is Kristi Eggers?
5	A. Eggers.
6	Q. Do you know how to spell her last name?
7	$A. \qquad E-G-G-E-R-S.$
8	Q. Just so I'm clear, she was a nurse
9	practitioner at the nursing home where you worked;
10	correct?
11	A. She was a nurse practitioner in the town
12	where I worked. She worked at one of the clinics.
13	The two doctors that she worked with were from
14	Henderson, Nebraska. They kind of share doctors.
15	Q. Do you know if Kristi spells her name with
16	a Y or an I-E, if you know?
17	A. K-R-I-S-T-I.
18	Q. I knew I left out one option there.
19	So I'm clear, Kristi Eggers was you
20	would call her a friend or acquaintance; right?
21	A. Yes, because I did work with her, yes.
22	Q. She was not a medical professional that
23	formally treated you?
24	A. Yes, she did.
25	Q. When did she treat you?

	Page 134
1	A. No.
2	MR. ARBON: Objection to form.
3	BY MR. NASH:
4	Q. After you talked with Kristi and she and
5	you talked about your filter and your abdominal
6	pain, did you then go talk to a physician about your
7	filter and your abdominal pain?
8	A. A physician other than Dr. Smith?
9	Q. Any physician.
10	A. Just Dr. Smith.
11	Q. So you went to go talk to Dr. Smith
12	towards the beginning of 2011; correct?
13	A. Yes.
14	Q. What do you recall in terms of the
15	conversation with Dr. Smith?
16	A. He said whenever you're ready to have the
17	filter out, we'll set up a time and you can come to
18	the hospital and we'll do it here and, you know, it
19	was kind of up to me to figure out the time.
20	(Exhibit No. 13
21	marked for identification.)
22	BY MR. NASH:
23	Q. I handed you Exhibit 13, and this is a
24	progress note. You see your name at the top, Carol
25	Kruse, and the date 3/14/11. Do you see that?

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1	A. I am looking for a 3/14. Yes.
2	Q. Top left-hand corner?
3	A. I got it right there.
4	This is from Kristi Eggers.
5	Q. Under sort of the middle of that first
6	page under "HPI," it says, "Patient is in today for
7	preop clearance. She is planning to have IVC filter
8	removed."
9	Do you see that?
10	A. Yes.
11	Q. "This has been causing her pain for the
12	last three or four months."
13	Do you see that?
14	A. Yes.
15	Q. Towards the end, under "Review of
16	Symptoms" in the middle of the page, do you see
17	where it says, musculo you can pronounce
18	A. Musculoskeletal.
19	Q. Yes. What does that say?
20	A. "Denies any joint or pain stiffness.
21	Positive low back pain as above."
22	Q. When it says, "positive low back pain as
23	above," do you think that's meant to refer to your
24	abdominal pain?
25	A. No.

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1	MR. ARBON: Objection to form.
2	BY MR. NASH:
3	Q. Were you experiencing low back pain as
4	well at that time period?
5	A. As a nurse that's pretty much a guarantee.
6	You're going to have back pain from lifting.
7	Q. But that low back pain is not pain that
8	you were associating with your IVC filter; right?
9	A. No.
10	Q. And I ask, you know, just out of
11	curiosity, because it says, "as above," and I assume
12	that's referring to the pain that we just read where
13	it says "causing her pain for the last three or four
14	months."
15	Is it your understanding it's referring to
16	two different pains that you were experiencing?
17	MR. ARBON: Objection to form.
18	THE WITNESS: Where does it say I was
19	having back pain except for where it says "positive
20	low back pain as above"? As above what? Where is
21	that at?
22	BY MR. NASH:
23	Q. That's what I was confused about. I was
24	curious if you were experiencing low back pain at
25	this time period. I believe your testimony is you

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1	were?
2	MR. ARBON: Objection to form.
3	MR. NASH: She just said that.
4	BY MR. NASH:
5	Q. Let me ask a different question,
6	Ms. Kruse.
7	Am I correct that you were having low back
8	pain at this time period?
9	A. If I was, it was not related to the
10	pain the abdominal pain.
11	Q. Under "Gastrointestinal," right above you
12	see where it says, "denies any loss of appetite or
13	abdominal pain"?
14	A. Right.
15	Q. Is that consistent with your recollection
16	of the pain you were experiencing?
17	A. That when a physician writes that, that
18	has to do more with digestive concerns. And I've
19	had no abdominal digestive problems.
20	Q. So I just want to make sure it's clear.
21	At this time period you were experiencing
22	the abdominal pain that you described before where
23	it would hurt when you twisted or bent certain ways;
24	right?
25	A. Correct.

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1	Q. And you were going in to get this preop
2	clearance to have your IVC filter removed?
3	A. Yes.
4	Q. And at this time period you had had
5	conversations with Kristi Eggers about potentially
6	my IVC filter is causing that pain; right?
7	A. Yes, abdominal pain.
8	Q. When you talked to Dr. Smith about having
9	your IVC filter removed do you remember that
10	conversation?
11	A. Yes.
12	Q. What do you remember from that
13	conversation?
14	A. He said, you know, whenever you are ready
15	to have it removed, set the date, and we'll do it
16	right here at the hospital.
17	(Exhibit No. 14
18	marked for identification.)
19	BY MR. NASH:
20	Q. Ms. Kruse, you've been handed Exhibit 14.
21	If you look on the second page, you see a signature.
22	Is that your signature in the middle of the page?
23	A. Yes, it is.
24	Q. Flip back to the front. It says, "Date of
25	Procedure: April 7, 2011." Correct?

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1	Q. Have you ever spoken to anyone at C.R.
2	Bard or Bard Peripheral Vascular?
3	A. No.
4	(Exhibit No. 16
5	marked for identification.)
6	MR. NASH: This is 16.
7	BY MR. NASH:
8	Q. Ms. Kruse, I've handed you Exhibit 16.
9	A. Yes.
10	Q. Do you recognize this document?
11	A. Yes.
12	Q. I just want to confirm, this is you at the
13	top, Carol D. Kruse; correct?
14	A. Correct.
15	Q. Dated February 5, 2013?
16	A. Yes.
17	Q. Is this a appear to you to be a true
18	and correct copy of the bankruptcy petition that was
19	filed on your behalf back in 2013?
20	A. Yes.
21	(Exhibit No. 17
22	marked for identification.)
23	BY MR. NASH:
24	Q. And, Ms. Kruse, you've been handed Exhibit
25	No. 17. Do you recognize this document?

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1	A. Yes.
2	Q. At the top it's dated filed June 6
3	I'm sorry, June 3rd, 2013. Do you see that?
4	A. Yes.
5	Q. And you see it says, "Discharge of
6	debtor"?
7	A. Yes.
8	Q. Do you understand I'm sorry, strike
9	that.
10	Towards the top you see where your name is
11	listed, "Carol D. Kruse"?
12	A. Yes.
13	Q. Do you understand this document to be a
14	true and correct copy of the discharge order related
15	to the bankruptcy filing we just looked at?
16	A. Yes.
17	MR. NASH: I don't have any further
18	questions.
19	CROSS-EXAMINATION
20	BY MR. ARBON:
21	Q. Let me ask you a quick question.
22	You just said have you ever contacted
23	Bard, counsel asked you that.
24	A. Right.
25	Q. Just to be clear, have you ever had any

REDACTED DOCUMENTS RELATED TO DOCKET 7341

Exhibit F - Filed Redacted



Deposition of: **Darren Robert Hurst**, **M.D.**

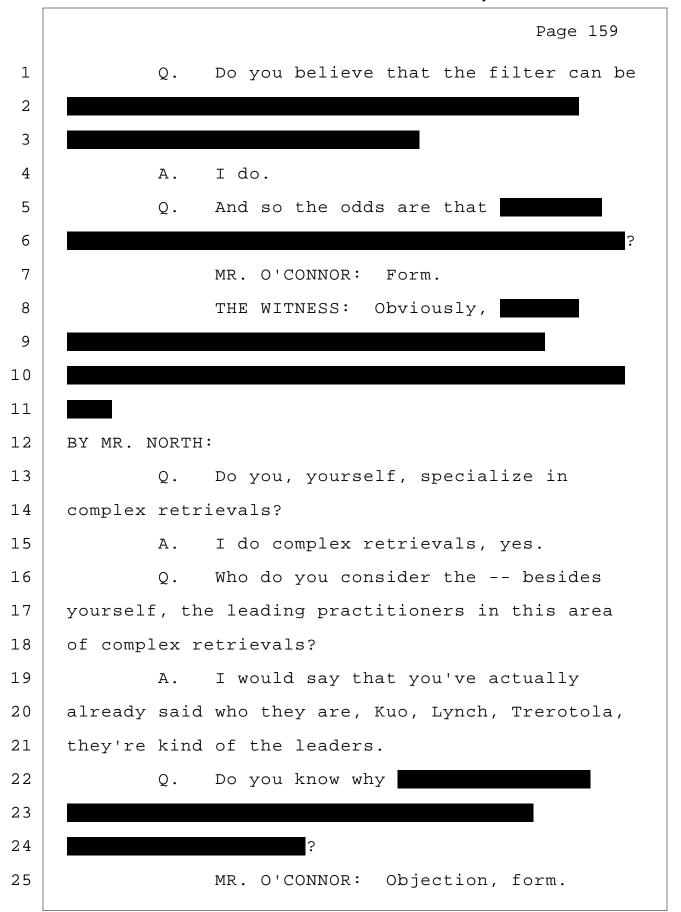
July 21, 2017

In the Matter of:

In Re: Bard IVC Filters Products Liability

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